

## REMARKS

In the Office Action of May 22, 2003, the specification was objected to for failing to provide antecedent basis for the words "deformable arcuate" used in the claims. Specifically, the specification was objected to because the word "deformable" was not used in the specification. Applicant respectfully submits that the word "deformable" is present in the specification and adequately defined. For example, the Examiner's attention is directed to the first full paragraph on page 10 of the present Application (see page 10, lines 10-15 of the present Application):

To further facilitate engagement, the adapter body 102 is preferably formed of flexible pvc or some other slightly deformable substance to maximize the area of the sidewall 148 which engages the distal end 164 of the infusion set 168. In addition to the above, depending on the configuration of the steps of the distal end 164, the arcuate sidewall 148 can actually engage an additional step, such as ring 164b to provide an even more secure hold of the distal end.

This language was pointed out by the Applicant in the previous Amendment mailed February 10, 2003.

As such, Applicant has explained that the adapter body 102 may be made of a deformable substance in order to facilitate engagement by maximizing the area of contact between the sidewall 148 and the distal end 164 of the infusion set 168. However, in order to ensure that there is no further confusion in regards to the words "deformable arcuate", Applicant has amended claim 1 such that it calls for "at least one arcuate sidewall being deformable" instead of the previously used "deformable arcuate sidewall". As such, Applicant respectfully submits that the specification of the current

Application provides for proper antecedent basis for the claimed subject matter and requests the objection be removed.

Also in the Office Action of May 22, 2003, the drawings were objected to for failing to show a medical feeding device. In the present Amendment, Applicant has removed any reference to the medical feeding device from the claims. As such, this feature has been cancelled from the claims and Applicant respectfully requests the objection to the drawings be removed.

In the Office Action, claim 1 was objected to for calling for a medical feeding device. Applicant has removed any reference to a medical feeding device from claim 1, and as such requests that this objection to the drawings be removed.

Further, in the Office Action of May 22, 2003, claims 1-23 were rejected under 35 U.S.C. § 112, first paragraph, for calling for a "deformable arcuate sidewall". Applicant has amended claim 1 in order to call for "at least one arcuate sidewall that is deformable", and has likewise amended claim 18 to call for "the first arcuate sidewall being deformable". Applicant respectfully submits that this subject matter is described at least in the previously mentioned first full paragraph on page 10 of the Application (see page 10, lines 10-15 of Applicant's Application). The specification clearly discloses an arcuate sidewall that is deformable. As such, Applicant respectfully requests the § 112, first paragraph rejection to claims 1-23 be removed.

Also in the Office Action of May 22, 2003, claims 1-23 were rejected under 35 U.S.C. § 112, second paragraph, for reciting the word "deformable" in line 6 of claims 1 and 18. As used in claims 1 and 18, the word "deformable" is not a new element of the enteral feeding adapter, but is instead an adjective that is used to describe "the at least

one arcuate sidewall". Claim 1 has been amended in order to more clearly state that the at least one arcuate sidewall is deformable. Similarly, claim 18 calls for the "first arcuate sidewall being deformable". Again, the word "deformable" is used to describe the first arcuate sidewall and is not a new element onto itself. As such, Applicant respectfully requests the § 112, second paragraph rejection to claims 1 and 18 be removed.

In the Office Action of May 22, 2003, claims 1, 2, 10, 13-15, and 18-21 were rejected under 35 U.S.C. § 102(e) as being anticipated by Prichard (U.S. Patent No. 5,988,700).

Additionally, claims 1, 3-7, 10, 11, 13-15, and 17-22 were rejected under 35 U.S.C. § 102(b) as being anticipated Oilschlager et al. (U.S. Patent No. 5,267,983).

Also in the Office Action, claims 8, 9, 12, 16, and 23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Oilschlager.

Applicant respectfully submits that Prichard does not disclose an enteral feeding adapter that has an adapter body with at least one arcuate sidewall that is deformable as claimed in claim 1 of Applicant's Application.

Prichard discloses a fluidic connector 10 into which a plug or male adapter may be inserted. The fluidic connector 10 includes a first portion 15 which is designed in order to receive a plug (see Prichard at column 4, lines 48-51). The fluidic connector 10 also includes a second portion 16 that is designed to receive a male adapter (see Prichard at column 4, lines 44-47). Between the first and second portions 15-16 there is disposed a deformable buckling region 19 (see Prichard at columns 4, lines 58-61).

Prichard notes that a problem in the art exists when male adapters too large, or not appropriately shaped, are inserted into fluidic connectors and cause the fluidic connectors to experience plastic deformation such that the connection site between the fluidic connector and the male adapter is overstretched (see Prichard at column 1, line 58 to column 2, line 12). This overstretching leads to a permanent disfigurement of the fluidic connector such that subsequent connections may no longer be securely fit. Additionally, this stretching and disfigurement causes a corresponding disfigurement of the portion of the fluidic connector to which the plug may be inserted during periods of disengagement of the male adapter to the fluidic connector. Because the fluidic connector was disfigured due to overstretching by the male adapter, the portion of the fluidic connector that receives the plug is likewise disfigured and results in a fluid leak when the plug is engaged to the fluidic connector.

The fluidic connector of Prichard is designed in order to reduce or eliminate the problem of overstretching or disfigurement in regards to the portion of the fluidic connector 10 that engages the plug. The solution that Prichard proposes is to provide for the buckling region 19 located between the first portion 15 (the portion that receives the plug) and the second portion 16 (the portion that receives the male adapter). Upon insertion of an inappropriately sized male adapter, the second portion 16 will be stretched and disfigured in a radial direction (see Fig. 5 of Prichard and column 5, lines 30-35). However, due to the presence of the deformable buckling region 19, the radial stretching and disfigurement of the second portion 16 is translated into only an axial stretching and disfigurement of the first portion 15 (see Figs. 5 and 6 of Prichard and

column 5, lines 45-57). Since the first portion 15 is not stretched or disfigured radially, the plug may be inserted therein and provide for an effective fluid seal.

Therefore, the stretching and disfigurement of the fluidic connector 10 is an undesirable consequence of placement of a male adapter into the fluidic connector. The overstretching and disfigurement is minimized by the presence of the buckling region 19 in order to prevent the first portion 15 from being overstretched or disfigured in a radial direction so that the plug that engages the first diameter portion 15 can still make an effective seal therewith. Therefore Prichard seeks to minimize the amount of overstretching or disfigurement brought about by the insertion of the male adapter into the fluid connector 10.

Turning now to one exemplary embodiment of the present invention, an enteral feeding adapter is provided that has an adapter body 102 with an arcuate sidewall 148 that is made of a deformable substance (see Applicant's Application at page 10, lines 10-15). The arcuate sidewall 148 is made of a deformable substance so that when the distal end 164 of infusion set 168 is inserted into the adapter body 102, the distal end 164 will deform the arcuate sidewall 148 so that a larger area of contact between these two components is realized to increase the frictional engagement therewith (see Applicant's Application at page 10, lines 10-15). The arcuate sidewall 148 is made of a material such as flexible pvc or another deformable substance such that the arcuate sidewall 148 may deform when force is applied thereto and then flex back to assume its original shape once the force is removed. As such, the deformation is actually desired, that is the deformation of the arcuate sidewall 148 actually helps to retain the distal end 164 of the infusion set 168 to the adapter body 102.

The first portion 15 and the second portion 16 of the fluidic connector 10 in Prichard are not deformable. These portions 15, 16 are rigid members that are stretched and disfigured due to the insertion of the male adapter. The first and second portions 15, 16 are not made of a deformable material, and do not regain their original shape once the male adapter is removed from the fluidic connector 10 (see Prichard at column 5, lines 30-34; and column 5, lines 53-56). In fact, Prichard explicitly contemplates that the first and second portions 15, 16 will be stretched and permanently disfigured. Further, buckling region 19 is not deformable for frictionally engaging the male adapter. The buckling region 19 is deformable in order to translate the radial stretching and disfigurement of the second portion 16 into an axial stretching and disfigurement of the first portion 15. The male adapter engages the second portion 16 and not the buckling region 19 (see Prichard at column 4, lines 44-47). Also, the buckling region 19 is not deformable so that the area of engagement between the male adapter and the buckling region 19 is increased. Likewise, neither the first or second portion 15, 16 is deformable so that the area of engagement between the male adapter and the first or second portion 15, 16 increases.

The overstretching and disfigurement of the second portion 16 is an undesirable effect brought about by forcing an inappropriately sized male adapter into the second portion 16. This overstretching and disfigurement also does not increase the area of engagement between the male adapter and the second portion 16. The exact same amount of area of contact on the second portion 16 is present if a properly sized male connector is inserted therein, and is the same area if an oversized male connector is inserted therein. The only difference is the fact that the position of the second portion

16 is moved outward in a radially direction due to the overstretching and disfigurement.

The male adapter is not frictionally engaged to the second portion 16 through deformation of the second portion 16, but is instead securely attached to the second portion 16 through an interference fit (see Prichard at column 4, lines 44-47). In stark contrast, the enteral feeding adapter of claim 1 calls for an adapter body with at least one arcuate sidewall that is deformable for frictionally engaging the distal connector. The arcuate sidewall is deformable so that the area of engagement between the distal connector and the arcuate sidewall is increased. As such, Applicant respectfully submits that claim 1 defines over Prichard.

As stated, claim 1 was also rejected under 35 U.S.C. § 102(b) as being anticipated by Oilschlager. Respectfully, Oilschlager does not disclose the enteral feeding adapter as set forth in claim 1 of Applicants' Application. Oilschlager discloses an adapter 12 with 5 cylindrical sections 12a, 12b, 12c, 12d, and 12e of different diameters (see Oilschlager at column 3, lines 15-18). The cylindrical section 12e is therefore on the outside of the adapter 12 and forms no portion of the central channel 38 that extends through the adapter 12. As can be seen in Fig. 4 of Oilschlager, the central channel 38 is a completely cylindrical passageway through the adapter 12.

In stark contrast, claim 1 of Applicant's Application calls for an enteral feeding adapter that has an adapter body with a first port where at least one arcuate sidewall defines a portion of a passageway through the first port. In Oilschlager, there are no arcuate sidewalls that define any portion of the central channel 38. As such, Oilschlager fails to disclose this feature claimed in claim 1.

Further, Oilschlager does not disclose a first port that has at least one arcuate sidewall that is deformable. Nowhere in Oilschlager is it stated that any component of the adapter 12 is deformable. In fact, the adapter 12 of Oilschlager is constructed in order to not be deformable. The adapter 12 is provided with the series of cylindrical sections 12a-12e in order to ensure that the adapter 12 is not inadvertently inserted into an inappropriate port. For instance, Fig. 8 shows the adapter 12 being inserted into a port 54 that is an IV port instead of an enteral feeding port. the port 54 is too rigid to open up and accept the cylindrical section 12b of the adapter (see Oilschlager at column 4, lines 14-17). If the cylindrical sections 12a - 12e of the adapter 12 were deformable, they would be able to deform and hence enter the port 54, causing the adapter 12 to be secured to the port 54. Of course, such an occurrence is specifically disfavored in Oilschlager which is in fact is directed towards an adapter 12 that cannot be deformed and hence inadvertently inserted into an IV port 54. The cylindrical sections 12a-12e are therefore rigid members of different sizes in order to ensure that the adapter 12 is not inserted into an incorrect port. If the cylindrical sections 12a-12e where in fact deformable, the adapter 12 could be force fit into an incorrect port hence completely frustrating the intended purpose of Oilschlager.

Further, Oilschlager does not disclose an enteral feeding adapter with an adapter body having at least one arcuate sidewall that is deformable in order to increase the area of engagement of the distal connector of the infusion set and the at least one arcuate sidewall. Again, there is no disclosure in Oilschlager of any portion being deformable, and in fact the reference specifically discloses the port 54 being rigid such that the adapter 12 may not be inadvertently inserted therein. The engagement of the



cylindrical sections 12a-12e into the access port 18 is effected through an interference fit.

Paragraph 7b of the Office Action of May 22, 2003 states that Oilschlager discloses a deformable arcuate sidewall because it is capable of becoming disfigured. Applicant admits that any object can become disfigured provided a significant enough force is imparted onto the object. However, Oilschlager does not disclose an arcuate sidewall that is deformable as claimed in claim 1 of Applicants' Application or as described on page 10, lines 10-15 of Applicant's specification. As such, Applicant respectfully submits that claim 1 defines over Oilschlager.

Therefore, Applicant respectfully submits that claim 1 defines over both Prichard and Oilschlager and is in condition for allowance. Further, all claims that depend either directly or indirectly from claim 1 (claims 2-17) are also in condition for allowance. Their rejections being made moot due to the allowance of claim 1.

Claim 18 also calls for a first arcuate sidewall that is deformable to frictionally engage the distal end of the infusion set to secure the distal end of the infusion set to the adapter body. Further, the first arcuate sidewall is deformable so that the area of engagement between the distal end of the infusion set and the first arcuate sidewall is increased. Therefore, Applicant submits that claim 18 defines over both Prichard and Oilschlager for essentially the same reasons as discussed above with respect to claim 1. Applicant respectfully submits that claim 18 is allowable and that all claims which depend either directly or indirectly from claim 18 (claims 19-23) are also allowable. Their rejections being made moot due to the allowance of claim 18.

With the present amendment, Applicant submits that all pending claims are allowable and that the Application is in condition for allowance. Favorable action thereon is respectfully requested. The Examiner is encouraged to contact the undersigned at the Examiner's convenience to resolve any remaining issues.

Respectfully submitted,

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